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PFIZER INC., PHARMACIA CORPORATION,  
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION

*This document relates to*

DANA CHIN, Individually and on Behalf of TATE  
MCALLISTER, Deceased,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,  
and G.D. SEARLE, LLC,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-4793-CRB

) **PFIZER INC., PHARMACIA**  
) **CORPORATION, AND G.D.**  
) **SEARLE LLC'S ANSWER TO**  
) **COMPLAINT**

) **JURY DEMAND ENDORSED**  
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as  
 2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC  
 3 (improperly captioned in Plaintiff's Complaint as "G.D. Searle, LLC") ("Searle"), (collectively  
 4 "Defendants") and file their Answer to Plaintiff's Complaint ("Complaint"), and would  
 5 respectfully show the Court as follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Decedent was prescribed or used  
 9 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted  
 10 generally. Defendants may seek leave to amend this Answer when discovery reveals the  
 11 specific time periods in which Decedent was prescribed and used Celebrex®.

12 **II.**

13 **ANSWER**

14 **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but  
 16 deny that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain  
 17 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United  
 18 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
 19 accordance with their approval by the FDA. Defendants admit that, during certain periods of  
 20 time, Celebrex® were manufactured and packaged for Searle, which developed, tested,  
 21 marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by  
 22 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
 23 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used  
 24 in accordance with its FDA-approved prescribing information. Defendants state that the  
 25 potential effects of Celebrex® were and are adequately described in its FDA-approved  
 26 prescribing information, which was at all times adequate and comported with applicable  
 27 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused  
 28

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1 Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 2. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's  
5 age and citizenship, Decedent's survivors, whether Plaintiff is the Personal Representative of  
6 Decedent's Estate, and whether Plaintiff is the proper party to bring an action of behalf of  
7 Decedent's estate, and, therefore, deny the same. Defendants deny the remaining allegations in  
8 this paragraph of the Complaint.

9 3. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
10 business in New York. Defendants admit that, as the result of a merger in April 2003,  
11 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph  
12 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants  
13 are without knowledge or information sufficient to form a belief as to the truth of such  
14 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of  
15 time, Pfizer marketed and co-promoted Celebrex® in the United States, including California  
16 and Nevada, to be prescribed by healthcare providers who are by law authorized to prescribe  
17 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
18 allegations in this paragraph of the Complaint.

19 4. Defendants admit that Searle is a Delaware limited liability company with its principal  
20 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,  
21 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
22 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
23 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
24 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
25 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
26 the remaining allegations in this paragraph of the Complaint.

27 5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of  
28 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as

1 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
2 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted  
3 Celebrex® in the United States, including California, to be prescribed by healthcare providers  
4 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 6. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a  
7 merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants deny  
8 the remaining allegations in this paragraph of the Complaint.

9 **Response to Allegations Regarding Jurisdiction and Venue**

10 7. Defendants are without knowledge or information to form a belief as to the truth of the  
11 allegations in this paragraph of the Complaint regarding the amount in controversy, and,  
12 therefore, deny that the same. However, Defendants admit that Plaintiff claims that the amount  
13 in controversy exceeds \$75,000, exclusive of interests and costs.

14 8. Defendants are without knowledge or information to form a belief as to the truth of the  
15 allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the amount  
16 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims  
17 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of  
18 interests and costs.

19 9. Defendants are without knowledge or information to form a belief as to the allegations  
20 in this paragraph of the Complaint regarding the judicial district in which the asserted claims  
21 allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe  
22 and effective when used in accordance with its FDA-approved prescribing information.  
23 Defendants deny committing a tort in the State of California and deny the remaining allegations  
24 in this paragraph of the Complaint.

25 10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
26 and co-promoted Celebrex® in the United States, including California and Nevada, to be  
27 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
28 with their approval by the FDA. Defendants admit that, during certain periods of time,

1 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-  
2 promoted and distributed Celebrex® in the United States to be prescribed by healthcare  
3 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
4 FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in  
5 the States of Nevada and California. Defendants state that the allegations in this paragraph of  
6 the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are  
7 without knowledge or information sufficient to form a belief as to the truth of such allegations,  
8 and, therefore, deny the same. Defendants deny committing a tort in the States of California  
9 and Nevada and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Allegations Regarding Interdistrict Assignment**

11 11. Defendants state that this paragraph of the Complaint contains legal contentions to  
12 which no response is required. To the extent that a response is deemed required, Defendants  
13 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.  
14 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial  
15 Panel on Multidistrict Litigation on September 6, 2005.

16 **Response to Factual Allegations**

17 12. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
19 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this  
20 paragraph of the Complaint.

21 13. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding Decedent’s medical  
23 condition and whether Decedent used Celebrex®, and, therefore, deny the same. Defendants  
24 deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or  
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 14. Defendants are without knowledge or information sufficient to form a belief as to the  
27 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
28 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants  
2 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
3 approved prescribing information, which was at all times adequate and comported with  
4 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
5 remaining allegations in this paragraph of the Complaint.

6 15. Defendants are without knowledge or information sufficient to form a belief as to the  
7 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
8 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
9 effective when used in accordance with its FDA-approved prescribing information. Defendants  
10 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
11 approved prescribing information, which was at all times adequate and comported with  
12 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
13 Celebrex® caused Plaintiff or Decedent injury or damage and deny the remaining allegations in  
14 this paragraph of the Complaint.

15 16. Defendants are without knowledge or information sufficient to form a belief as to the  
16 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
17 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,  
18 Celebrex® was expected to reach users and consumers without substantial change from the  
19 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 17. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
22 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
23 effective when used in accordance with its FDA-approved prescribing information. Defendants  
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
25 approved prescribing information, which was at all times adequate and comported with  
26 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
27 remaining allegations in this paragraph of the Complaint.

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18. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the remaining allegations in this paragraph of the Complaint.

19. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

20. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

21. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

22. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

23. Defendants state that the allegations in this paragraph of the Complaint regarding “other pharmaceutical companies” are not directed towards Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the



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1 FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to  
2 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2  
3 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the  
4 cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to provide the proper context for the  
5 remaining allegations in this paragraph and Defendants therefore lack sufficient information or  
6 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining  
7 allegations in this paragraph of the Complaint.

8 24. Defendants state that the allegations in this paragraph of the Complaint regarding  
9 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or  
10 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
11 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he  
12 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,  
13 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in  
14 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants  
15 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
16 approved prescribing information. Defendants state that the potential effects of Celebrex®  
17 were and are adequately described in its FDA-approved prescribing information, which was at  
18 all times adequate and comported with applicable standards of care and law. Defendants deny  
19 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

20 25. Defendants admit that Searle submitted a New Drug Application (“NDA”) for  
21 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted  
22 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of  
23 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.  
24 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to  
25 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis  
26 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny  
27 the remaining allegations in this paragraph of the Complaint.

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26. Defendants admit that Celebrex® was launched in February 1999. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

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1 30. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 31. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA  
8 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to  
9 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,  
10 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself  
11 and respectfully refer the Court to the study for its actual language and text. Any attempt to  
12 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
13 the Complaint.

14 32. Defendants state that the referenced Medical Officer Review speaks for itself and  
15 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
16 attempt to characterize the Medical Officer Review is denied. Defendants state that the  
17 referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court  
18 to the Alert for Healthcare Professionals for its actual language and text. Any attempt to  
19 characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining  
20 allegations in this paragraph of the Complaint.

21 33. Defendants state that the referenced study speaks for itself and respectfully refer the  
22 Court to the study for its actual language and text. Any attempt to characterize the study is  
23 denied. Defendants state that the referenced article speaks for itself and respectfully refer the  
24 Court to the article for its actual language and text. Any attempt to characterize the article is  
25 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
26 paragraph of the Complaint.

27 34. Defendants state that the referenced Medical Officer Review speaks for itself and  
28 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any

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1 attempt to characterize the Medical Officer Review is denied. Defendants state that the  
2 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
3 language and text. Any attempt to characterize the article is denied. Defendants deny the  
4 remaining allegations in this paragraph of the Complaint.

5 35. Defendants state that the referenced article speaks for itself and respectfully refer the  
6 Court to the article for its actual language and text. Any attempt to characterize the article is  
7 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
8 paragraph of the Complaint.

9 36. Defendants state that the referenced articles speak for themselves and respectfully refer  
10 the Court to the articles for their actual language and text. Any attempt to characterize the  
11 articles is denied. Defendants state that the referenced study speaks for itself and respectfully  
12 refer the Court to the study for its actual language and text. Any attempt to characterize the  
13 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 37. Defendants state that the referenced Medical Officer Review speaks for itself and  
15 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
16 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
17 allegations in this paragraph of the Complaint.

18 38. Plaintiff fails to provide the proper context for the allegations concerning "Public  
19 Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
20 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 39. Defendants state that the referenced study speaks for itself and respectfully refer the  
23 Court to the study for its actual language and text. Any attempt to characterize the study is  
24 denied. Plaintiff fails to provide the proper context for the allegations concerning "Public  
25 Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
26 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
27 Defendants deny the remaining allegations in this paragraph of the Complaint.  
28

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1 40. Defendants admit that there was a clinical trial called APC. Defendants state that the  
2 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
3 language and text. Any attempt to characterize the article is denied. Defendants deny the  
4 remaining allegations in this paragraph of the Complaint.

5 41. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
6 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
7 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
8 Defendants deny the remaining allegations in this paragraph of the Complaint.

9 42. Defendants state that the referenced Medical Officer Review speaks for itself and  
10 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
11 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
12 allegations in this paragraph of the Complaint.

13 43. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide  
14 the proper context for the allegations concerning “other Celebrex trials” contained in this  
15 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
16 form a belief as to the truth of such allegations and, therefore, deny the same. As for the  
17 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state  
18 that the referenced study speaks for itself and respectfully refer the Court to the study for its  
19 actual language and text. Any attempt to characterize the study is denied. Defendants deny the  
20 remaining allegations in this paragraph of the Complaint.

21 44. Defendants state that the referenced article speaks for itself and respectfully refer the  
22 Court to the article for its actual language and text. Any attempt to characterize the article is  
23 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

24 45. Plaintiff fails to provide the proper context for the allegations in this paragraph of the  
25 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants  
26 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
27 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for  
28 themselves and respectfully refer the Court to the studies for their actual language and text.

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1 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in  
2 this paragraph of the Complaint.

3 46. Defendants state that the referenced Medical Officer Review speaks for itself and  
4 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
5 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
6 allegations in this paragraph of the Complaint.

7 47. Defendants state that allegations in this paragraph of the Complaint regarding Vioxx®  
8 in this paragraph of the Complaint are not directed toward Defendants, and therefore no  
9 response is required. To the extent that a response is deemed required, Plaintiff fails to provide  
10 the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in  
11 this paragraph of the Complaint. Defendants therefore lack sufficient information or  
12 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
13 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
14 the study for its actual language and text. Any attempt to characterize the study is denied.  
15 Defendants deny the remaining allegations in this paragraph of the Complaint.

16 48. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
17 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and  
18 therefore no response is required. To the extent that a response is deemed required, Plaintiff  
19 fails to provide the proper context for the allegations in this paragraph of the Complaint  
20 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
21 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
22 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
23 respectfully refer the Court to the study for its actual language and text. Any attempt to  
24 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
25 the Complaint.

26 49. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
27 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and  
28 therefore no response is required. To the extent that a response is deemed required, Plaintiff

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1 fails to provide the proper context for the allegations in this paragraph of the Complaint  
2 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
3 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
4 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
5 respectfully refer the Court to the study for its actual language and text. Any attempt to  
6 characterize the study is denied. Defendants state that the referenced article speaks for itself  
7 and respectfully refer the Court to the article for its actual language and text. Any attempt to  
8 characterize the article is denied. Defendants deny the remaining allegations in this paragraph  
9 of the Complaint.

10 50. Defendants state that Celebrex® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants deny the allegations in this  
12 paragraph of the Complaint.

13 51. Defendants state that the referenced article speaks for itself and respectfully refer the  
14 Court to the article for its actual language and text. Any attempt to characterize the article is  
15 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 52. Defendants state that allegations in this paragraph of the Complaint are not directed  
17 toward Defendants, and therefore no response is required. To the extent that a response is  
18 deemed required, Defendants state that the referenced article speaks for itself and respectfully  
19 refer the Court to the article for its actual language and text. Any attempt to characterize the  
20 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 53. Defendants deny the allegations in this paragraph of the Complaint.

22 54. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
27 remaining allegations contained in this paragraph of the Complaint.

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1 55. Defendants deny any wrongful conduct and deny the allegations contained in this  
2 paragraph of the Complaint.

3 56. Defendants deny any wrongful conduct and deny the allegations contained in this  
4 paragraph of the Complaint.

5 57. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny any wrongful conduct and deny the remaining allegations contained in this  
10 paragraph of the Complaint.

11 58. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
14 effective when used in accordance with its FDA-approved prescribing information. Defendants  
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
16 approved prescribing information, which was at all times adequate and comported with  
17 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
18 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of  
19 the Complaint.

20 59. Defendants admit that the FDA Division of Drug Marketing, Advertising, and  
21 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state  
22 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its  
23 actual language and text. Any attempt to characterize the letter is denied. Defendants admit  
24 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the  
25 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual  
26 language and text. Any attempt to characterize the letter is denied. Defendants state that the  
27 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and  
28 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to



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1 characterize the transcripts is denied. Defendants state that the referenced study speaks for  
2 itself and respectfully refer the Court to the article for its actual language and text. Any attempt  
3 to characterize the article is denied. Defendants deny the remaining allegations in this  
4 paragraph of the Complaint.

5 60. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
10 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
11 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
12 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
13 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
14 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
15 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
16 allegations in this paragraph of the Complaint.

17 61. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
22 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
23 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
24 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
25 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
26 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
27 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a  
28 prescription medication which is approved by the FDA for the following indications: (1) for

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1 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of  
2 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the  
3 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps  
4 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic  
5 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for  
6 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age  
7 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this  
8 paragraph of the Complaint.

9 62. Defendants state that Celebrex® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
12 which at all times was adequate and comported with applicable standards of care and law.  
13 Defendants state that Plaintiff's allegations in this paragraph of the Complaint regarding  
14 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
15 information to form a belief as to the truth of such allegations, and, therefore, deny the same.  
16 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
17 allegations in this paragraph of the Complaint.

18 63. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants state that the potential effects of  
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
23 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
24 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
25 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
26 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
27 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
28

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1 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
2 allegations in this paragraph of the Complaint.

3 64. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which at all times was adequate and comported with applicable standards of care and law.  
7 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
8 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
9 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
10 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
11 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
12 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
13 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
14 allegations in this paragraph of the Complaint.

15 65. Defendants state that Celebrex® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants state that the potential effects of  
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
20 the Complaint.

21 66. Defendants state that Celebrex® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.  
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
26 the Complaint.

27 67. Defendants deny the allegations in this paragraph of the Complaint.  
28

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68. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

70. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

72. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 73. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® are and were adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
8 the study for its actual language and text. Any attempt to characterize the study is denied.  
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
10 the Complaint.

11 74. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
14 effective when used in accordance with its FDA-approved prescribing information. Defendants  
15 state that the potential effects of Celebrex® are and were adequately described in its FDA-  
16 approved prescribing information, which was at all times adequate and comported with  
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
18 remaining allegations in this paragraph of the Complaint.

19 **Response to First Cause of Action: Negligence**

20 75. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
21 Complaint as if fully set forth herein.

22 76. Defendants state that this paragraph of the Complaint contains legal contentions to  
23 which no response is required. To the extent that a response is deemed required, Defendants  
24 admit that they had duties as are imposed by law but deny having breached such duties.  
25 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
26 FDA-approved prescribing information. Defendants state that the potential effects of  
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 77. Defendants state that this paragraph of the Complaint contains legal contentions to  
4 which no response is required. To the extent that a response is deemed required, Defendants  
5 admit that they had duties as are imposed by law but deny having breached such duties.  
6 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
7 FDA-approved prescribing information. Defendants state that the potential effects of  
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
11 the Complaint.

12 78. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
14 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
15 effective when used in accordance with its FDA-approved prescribing information. Defendants  
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
17 approved prescribing information, which was at all times adequate and comported with  
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
19 remaining allegations in this paragraph of the Complaint, including all subparts.

20 79. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
22 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
23 effective when used in accordance with its FDA-approved prescribing information. Defendants  
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
25 approved prescribing information, which was at all times adequate and comported with  
26 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
27 remaining allegations in this paragraph of the Complaint.

28

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1 80. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 81. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
10 effective when used in accordance with its FDA-approved prescribing information. Defendants  
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
12 approved prescribing information, which was at all times adequate and comported with  
13 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
14 Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations  
15 in this paragraph of the Complaint.

16 82. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
18 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that  
19 Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations  
20 in this paragraph of the Complaint.

21 83. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
22 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
23 Complaint.

24 84. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
25 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
26 Complaint.

27  
28



**Response to Second Cause of Action: Strict Liability**

85. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

86. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

87. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

88. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the  
4 remaining allegations in this paragraph of the Complaint, including all subparts.

5 90. Defendants are without knowledge or information sufficient to form a belief as to the  
6 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
8 effective when used in accordance with its FDA-approved prescribing information. Defendants  
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
10 approved prescribing information, which was at all times adequate and comported with  
11 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
12 Celebrex® is defective, deny that Celebrex® caused Plaintiff or Decedent injury or damage,  
13 and deny the remaining allegations in this paragraph of the Complaint.

14 91. Defendants state that Celebrex® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
19 remaining allegations in this paragraph of the Complaint.

20 92. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
22 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
23 effective when used in accordance with its FDA-approved prescribing information. Defendants  
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
25 approved prescribing information, which was at all times adequate and comported with  
26 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
27 Celebrex® is defective, deny that Celebrex® caused Plaintiff or Decedent injury or damage,  
28 and deny the remaining allegations in this paragraph of the Complaint.

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1 93. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 94. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
10 effective when used in accordance with its FDA-approved prescribing information. Defendants  
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
12 approved prescribing information, which was at all times adequate and comported with  
13 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
14 Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations  
15 in this paragraph of the Complaint.

16 95. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 96. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
25 effective when used in accordance with its FDA-approved prescribing information. Defendants  
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
27 approved prescribing information, which was at all times adequate and comported with  
28

1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
2 remaining allegations in this paragraph of the Complaint.

3 97. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
4 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
5 Complaint.

6 98. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
7 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
8 Complaint.

9 99. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
10 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
11 Complaint.

12 **Response to Third Cause of Action: Breach of Express Warranty**

13 100. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
14 Complaint as if fully set forth herein.

15 101. Defendants are without knowledge or information sufficient to form a belief as to the  
16 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
17 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
18 effective when used in accordance with its FDA-approved prescribing information. Defendants  
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
20 approved prescribing information, which was at all times adequate and comported with  
21 applicable standards of care and law. Defendants admit that they provided FDA-approved  
22 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in  
23 this paragraph of the Complaint.

24 102. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
26 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
27 effective when used in accordance with its FDA-approved prescribing information. Defendants  
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

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1 approved prescribing information, which was at all times adequate and comported with  
2 applicable standards of care and law. Defendants admit that they provided FDA-approved  
3 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and  
4 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

5 103. Defendants admit that they provided FDA-approved prescribing information regarding  
6 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this  
7 paragraph of the Complaint.

8 104. Defendants state that Celebrex® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
11 which was at all times adequate and comported with applicable standards of care and law.  
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
13 the Complaint.

14 105. Defendants state that Celebrex® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
19 the Complaint.

20 106. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
22 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of  
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.  
25 Defendants admit that they provided FDA-approved prescribing information regarding  
26 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

1 107. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
 2 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
 3 Complaint.

4 108. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
 5 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
 6 Complaint.

7 109. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
 8 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
 9 Complaint.

10 **Response to Fourth Cause of Action: Breach of Implied Warranty**

11 110. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
 12 Complaint as if fully set forth herein.

13 111. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
 14 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
 15 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
 16 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
 17 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
 18 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
 19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
 20 the remaining allegations in this paragraph of the Complaint.

21 112. Defendants state that Celebrex® was and is safe and effective when used in accordance  
 22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
 23 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
 24 which was at all times adequate and comported with applicable standards of care and law.  
 25 Defendants admit that they provided FDA-approved prescribing information regarding  
 26 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 113. Defendants state that Celebrex® was and is safe and effective when used in accordance  
 28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 114. Defendants state that Celebrex® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny the remaining allegations in this paragraph of the Complaint.

9 115. Defendants state that Celebrex® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
12 which was at all times adequate and comported with applicable standards of care and law.  
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 116. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
16 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
17 effective when used in accordance with its FDA-approved prescribing information. Defendants  
18 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
19 approved prescribing information, which was at all times adequate and comported with  
20 applicable standards of care and law. Defendants admit that they provided FDA-approved  
21 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in  
22 this paragraph of the Complaint.

23 117. Defendants are without knowledge or information sufficient to form a belief as to the  
24 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
25 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,  
26 Celebrex® was expected to reach users and consumers without substantial change from the  
27 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.  
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1 118. Defendants are without knowledge or information sufficient to form a belief as to the  
2 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
3 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
4 effective when used in accordance with its FDA-approved prescribing information. Defendants  
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
6 approved prescribing information, which was at all times adequate and comported with  
7 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they  
8 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

9 119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
10 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
11 Complaint.

12 120. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
13 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
14 Complaint.

15 121. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
16 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
17 Complaint.

18 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

19 122. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
20 Complaint as if fully set forth herein.

21 123. Defendants state that this paragraph of the Complaint contains legal contentions to  
22 which no response is required. To the extent that a response is deemed required, Defendants  
23 admit that they had duties as are imposed by law but deny having breached such duties.  
24 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
25 FDA-approved prescribing information. Defendants state that the potential effects of  
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 124. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint, including all subparts.

9 125. Defendants state that Celebrex® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
12 which was at all times adequate and comported with applicable standards of care and law.  
13 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
14 the Complaint.

15 126. Defendants are without knowledge or information sufficient to form a belief as to the  
16 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
17 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
18 effective when used in accordance with its FDA-approved prescribing information. Defendants  
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
20 approved prescribing information, which was at all times adequate and comported with  
21 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
22 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this  
23 paragraph of the Complaint.

24 127. Defendants state that Celebrex® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants state that the potential effects of  
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 128. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
5 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
6 effective when used in accordance with its FDA-approved prescribing information. Defendants  
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
8 approved prescribing information, which was at all times adequate and comported with  
9 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
10 remaining allegations in this paragraph of the Complaint.

11 129. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
14 effective when used in accordance with its FDA-approved prescribing information. Defendants  
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
16 approved prescribing information, which was at all times adequate and comported with  
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
18 remaining allegations in this paragraph of the Complaint.

19 130. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
22 effective when used in accordance with its FDA-approved prescribing information. Defendants  
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
24 approved prescribing information, which was at all times adequate and comported with  
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
26 remaining allegations in this paragraph of the Complaint.

27 131. Defendants are without knowledge or information sufficient to form a belief as to the  
28 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used

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1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
2 effective when used in accordance with its FDA-approved prescribing information. Defendants  
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
4 approved prescribing information, which was at all times adequate and comported with  
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
6 remaining allegations in this paragraph of the Complaint.

7 132. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
10 effective when used in accordance with its FDA-approved prescribing information. Defendants  
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
12 approved prescribing information, which was at all times adequate and comported with  
13 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
14 remaining allegations in this paragraph of the Complaint.

15 133. Defendants are without knowledge or information sufficient to form a belief as to the  
16 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
17 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
18 effective when used in accordance with its FDA-approved prescribing information. Defendants  
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
20 approved prescribing information, which was at all times adequate and comported with  
21 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
22 remaining allegations in this paragraph of the Complaint.

23 134. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
24 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
25 Complaint.

26 135. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
27 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
28 Complaint.

1 136. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
2 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
3 Complaint.

4 **Response to Sixth Cause of Action: Unjust Enrichment**

5 137. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
6 Complaint as if fully set forth herein.

7 138. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
8 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
9 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
10 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
11 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
14 the remaining allegations in this paragraph of the Complaint.

15 139. Defendants are without knowledge or information sufficient to form a belief as to the  
16 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
17 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this  
18 paragraph of the Complaint.

19 140. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
21 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this  
22 paragraph of the Complaint.

23 141. Defendants are without knowledge or information sufficient to form a belief as to the  
24 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
25 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
26 effective when used in accordance with its FDA-approved prescribing information. Defendants  
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
28 approved prescribing information, which was at all times adequate and comported with

1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
2 remaining allegations in this paragraph of the Complaint.

3 142. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding whether Decedent used  
5 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
6 effective when used in accordance with its FDA-approved prescribing information. Defendants  
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
8 approved prescribing information, which was at all times adequate and comported with  
9 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
10 remaining allegations in this paragraph of the Complaint.

11 143. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
12 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
13 Complaint.

14 **Response to Seventh Cause of Action:**

15 **State Consumer Fraud and Deceptive Trade Practices Act**

16 144. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
17 Complaint as if fully set forth herein.

18 145. Defendants state that this paragraph of the Complaint contains legal contentions to  
19 which no response is required. To the extent that a response is deemed required, Defendants  
20 admit that they had duties as are imposed by law but deny having breached such duties.  
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 146. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations regarding whether Decedent used Celebrex® and, therefore, deny the  
24 same. Defendants state that Celebrex® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants state that the potential effects of  
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 147. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations regarding whether Decedent used Celebrex® and, therefore, deny the  
5 same. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent  
10 injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

11 148. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations regarding whether Decedent used Celebrex® and, therefore, deny the  
13 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 149. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations regarding whether Decedent used Celebrex® and, therefore, deny the  
16 same. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 150. Defendants state that this paragraph of the Complaint contains legal contentions to  
23 which no response is required. To the extent that a response is deemed required, Defendants  
24 deny any wrongful conduct and deny the remaining allegations in this paragraph of the  
25 Complaint.

26 151. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
27 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
28 Complaint.



1 152. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
 2 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
 3 Complaint.

4 153. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
 5 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
 6 Complaint.

7 154. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
 8 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
 9 Complaint.

10 155. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or  
 11 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
 12 Complaint.

### 13 **Response to Prayer for Relief**

14 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent  
 15 injury or damage, and deny the remaining allegations in paragraph of the Complaint headed  
 16 “Prayer for Relief,” including all subparts.

### 17 **III.**

### 18 **GENERAL DENIAL**

19 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff’s  
 20 Complaint that have not been previously admitted, denied, or explained.

### 21 **IV.**

### 22 **AFFIRMATIVE DEFENSES**

23 Defendants reserve the right to rely upon any of the following or additional defenses to  
 24 claims asserted by Plaintiff to the extent that such defenses are supported by information  
 25 developed through discovery or evidence at trial. Defendants affirmatively show that:

### 26 **First Defense**

27 1. The Complaint fails to state a claim upon which relief can be granted.  
 28

1 **Second Defense**

2 2. Celebrex® is a prescription medical product. The federal government has preempted  
3 the field of law applicable to the labeling and warning of prescription medical products.  
4 Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable  
5 federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon  
6 which relief can be granted; such claims, if allowed, would conflict with applicable federal law  
7 and violate the Supremacy Clause of the United States Constitution.

8 **Third Defense**

9 3. At all relevant times, Defendants provided proper warnings, information and  
10 instructions for the drug in accordance with generally recognized and prevailing standards in  
11 existence at the time.

12 **Fourth Defense**

13 4. At all relevant times, Defendants' warnings and instructions with respect to the use of  
14 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of  
15 knowledge at the time the drug was manufactured, marketed and distributed.

16 **Fifth Defense**

17 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the  
18 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

19 **Sixth Defense**

20 6. Plaintiff's action is barred by the statute of repose.

21 **Seventh Defense**

22 7. Plaintiff's claims against Defendants are barred to the extent Plaintiff and Decedent  
23 were contributorily negligent, actively negligent or otherwise failed to mitigate their damages,  
24 and any recovery by Plaintiff should be diminished accordingly.

25 **Eighth Defense**

26 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or  
27 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the  
28

1 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not  
2 liable in any way.

### 3 **Ninth Defense**

4 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,  
5 intervening causes for which Defendants cannot be liable.

### 6 **Tenth Defense**

7 10. Any injuries or expenses incurred by Plaintiff and Decedent were not caused by  
8 Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction,  
9 operation of nature, or act of God.

### 10 **Eleventh Defense**

11 11. Defendants affirmatively deny that they violated any duty owed to Plaintiff or Decedent.

### 12 **Twelfth Defense**

13 12. A manufacturer has no duty to warn patients or the general public of any risk,  
14 contraindication, or adverse effect associated with the use of a prescription medical product.  
15 Rather, the law requires that all such warnings and appropriate information be given to the  
16 prescribing physician and the medical profession, which act as a “learned intermediary” in  
17 determining the use of the product. Celebrex® is a prescription medical product, available only  
18 on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff’s  
19 and Decedent’s treating and prescribing physicians.

### 20 **Thirteenth Defense**

21 13. The product at issue was not in a defective condition or unreasonably dangerous at the  
22 time it left the control of the manufacturer or seller.

### 23 **Fourteenth Defense**

24 14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit  
25 for its intended use and the warnings and instructions accompanying Celebrex® at the time of  
26 the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

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**Fifteenth Defense**

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff and Decedent was prepared in accordance with the applicable standard of care.

**Sixteenth Defense**

16. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

**Seventeenth Defense**

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

**Eighteenth Defense**

18. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

**Nineteenth Defense**

19. Plaintiff and Decedent knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

**Twentieth Defense**

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

**Twenty-first Defense**

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**Twenty-second Defense**

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

**Twenty-third Defense**

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

**Twenty-fourth Defense**

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**Twenty-fifth Defense**

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

**Twenty-sixth Defense**

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**Twenty-seventh Defense**

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

**Twenty-eighth Defense**

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

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**Twenty-ninth Defense**

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

**Thirtieth Defense**

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of South Carolina, Arkansas, Wisconsin, Mississippi, and Minnesota, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

**Thirty-first Defense**

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

**Thirty-second Defense**

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

**Thirty-third Defense**

33. Plaintiff's punitive damage claims are preempted by federal law.

**Thirty-fourth Defense**

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

**Thirty-fifth Defense**

35. Plaintiff and Decedent failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

**Thirty-sixth Defense**

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

**Thirty-seventh Defense**

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**Thirty-eighth Defense**

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of South Carolina, Arkansas, Wisconsin, Mississippi, and Minnesota. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff or Decedent; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff or Decedent and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111



(1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

#### **Thirty-ninth Defense**

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

#### **Fortieth Defense**

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

#### **Forty-first Defense**

41. If Plaintiff and Decedent have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

#### **Forty-second Defense**

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

#### **Forty-third Defense**

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

#### **Forty-fourth Defense**

44. Plaintiff's claims are barred because Plaintiff's and Decedent's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions,

1 diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff  
2 and Decedent, and were independent of or far removed from Defendants' conduct.

3 **Forty-fifth Defense**

4 45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®  
5 did not proximately cause injuries or damages to Plaintiff and Decedent.

6 **Forty-sixth Defense**

7 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff  
8 and Decedent did not incur any ascertainable loss as a result of Defendants' conduct.

9 **Forty-seventh Defense**

10 47. The claims asserted in the Complaint are barred, in whole or in part, because the  
11 manufacturing, labeling, packaging, and any advertising of the product complied with the  
12 applicable codes, standards and regulations established, adopted, promulgated or approved by  
13 any applicable regulatory body, including but not limited to the United States, any state, and  
14 any agency thereof.

15 **Forty-eighth Defense**

16 48. The claims must be dismissed because Plaintiff and Decedent would have taken  
17 Celebrex® even if the product labeling contained the information that Plaintiff contends should  
18 have been provided.

19 **Forty-ninth Defense**

20 49. The claims asserted in the Complaint are barred because the utility of Celebrex®  
21 outweighed its risks.

22 **Fiftieth Defense**

23 50. Plaintiff's damages, if any, are barred or limited by the payments received from  
24 collateral sources.

25 **Fifty-first Defense**

26 51. Defendants' liability, if any, can only be determined after the percentages of  
27 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if  
28 any, are determined. Defendants seek an adjudication of the percentage of fault of the

claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff and Decedent.

**Fifty-second Defense**

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

**Fifty-third Defense**

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

**Fifty-fourth Defense**

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

**Fifty-fifth Defense**

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

**Fifty-sixth Defense**

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiff and Decedent were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiff's

1 recovery against Defendants, if any, should be reduced pursuant to California Civil Code §  
2 1431.2.

3 **Fifty-seventh Defense**

4 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of  
5 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil  
6 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive  
7 damages is also barred under California Civil Code § 3294(b).

8 **Fifty-eighth Defense**

9 58. Plaintiff's claims are barred, in whole or in part, pursuant to South Carolina Code Ann.  
10 § 15-3-20.

11 **Fifty-ninth Defense**

12 59. Defendants state that any award of punitive damages in this case would violate  
13 Defendants' procedural and substantive due process rights because there are insufficient  
14 circumstances in this case to support the reasonableness of an award of punitive damages and  
15 there are inadequate legal and procedural constraints imposed on the fact finder's discretion to  
16 impose such awards. The standard for punitive damages in Nevada lacks sufficient objective  
17 criteria and procedural safeguards to give a jury adequate criteria or an appropriate range of  
18 proportionality regarding punitive damages.

19 **Sixtieth Defense**

20 60. Defendants state that post-trial procedures and standards in a trial court for scrutinizing  
21 punitive damage awards and standards for appellate review of punitive damage awards in  
22 Nevada are insufficient, and therefore violate Defendants' rights to due process of law and right  
23 to protection from "excessive fines".

24 **Sixty-first Defense**

25 61. Defendants state that it would violate Defendants' rights guaranteed by the United  
26 States Constitution and the Constitution of the State of Nevada to impose punitive damages  
27 against them which are penal in nature by requiring a burden of proof on the Plaintiff which is  
28 less than the "beyond a reasonable doubt" burden of proof required in criminal cases. In the

1 alternative, entitlement to such damages would be provided by a “clear” and “convincing”  
2 standard of proof, in view of insufficient substantive and procedural protections under Nevada  
3 law regarding punitive damages.

4 **Sixty-second Defense**

5 62. Plaintiff’s claim for punitive damages is barred to the extent it exceeds the limitations  
6 imposed by N.R.S. § 42.005 or seeks punitive damages that are disproportionate to Plaintiff’s  
7 claims for compensatory damages.

8 **Sixty-third Defense**

9 63. To the extent Plaintiff seeks recovery for economic loss, recovery is limited to the  
10 reasonable damages contemplated by the parties and proximately caused by the breach pursuant  
11 to N.R.S. § 104.2715.

12 **Sixty-fourth Defense**

13 64. Defendants assert and preserve all statutory defenses available under the laws of the  
14 Commonwealth of Nevada, including but not limited to N.R.S. § 41.085 otherwise known as  
15 Nevada’s wrongful death statute.

16 **Sixty-fifth Defense**

17 65. Plaintiff lacks standing to bring a claim pursuant to N.R.S. §§ 41.600, 598.0915,  
18 598.0923 and 598.0925.

19 **Sixty-sixth Defense**

20 66. The conduct of Defendants and all activities with respect to Celebrix® were fair and  
21 truthful based upon the state of knowledge existing at the relevant time alleged in the  
22 Complaint. Therefore, Plaintiff’s claims under N.R.S. §§ 41.600, 598.0915, 598.0923, and  
23 598.0925 are barred.

24 **Sixty-seventh Defense**

25 67. All activities of Defendants as alleged in the Complaint were expressly permitted by  
26 federal statutes and regulations. Accordingly, as a matter of law, such activities cannot be  
27 deemed unfair, fraudulent, or unlawful under N.R.S. §§ 41.600, 598.0915, 598.0923, and  
28 598.0925.

**Sixty-eighth Defense**

68. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

**V.**

**PRAYER**

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff takes nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's and Decedent's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's and Decedent's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

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December 12, 2007

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**JURY DEMAND**

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

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